

Attorney Docket No. 408-016A

REMARKS

The Examiner has maintained the previous rejections. Reconsideration and withdrawal of the rejections is respectfully requested in view of the following remarks.

Applicants express their appreciation for the telephone interview conducted with Applicants' undersigned attorney by Examiner Deborah K. Ware and Primary Examiner David M. Naff on April 7, 2006. During the interview, the nature of the claimed invention was discussed, and it was explained to that the claimed medium comprises amino acids that are not in a solubilized state, i.e., that are not in solution, but that are in particulate form, and free from human and nonhuman substances, in comparison to the cited references, which disclose, e.g., moist dog food, amino acid solutions, and dried shrimp and liver powder. The Declaration Under 37 CFR 1.132 of Dr. Thierry Batard, previously made of record, was discussed as confirming that the results provided by the instant claimed invention were unexpected and nonobvious.

The Examiners explained that with a showing of support for the claim limitations, and absent a teaching of the medium as defined by the claims in the cited or in any newly uncovered art, the claims would be in condition for allowance. The following remarks address the specific points raised in the Office Action mailed on January 23, 2006, as well as explaining and/or recapitulating the basis for support for the elements of claim 1.

CLAIM AMENDMENTS

Claims 1-10, 12-15 and 20 are pending. Claim 1 is amended to move the text that was alleged to be a nonlimiting preamble into the body of the claim ("free from human or animal substances"), and to more particularly clarify that the claimed medium is in particulate form. It is respectfully urged that no new matter is added, since the examples of the specification clearly set forth the preparation of a particulate culture medium (see, e.g., Example 1, and especially page 6, lines 16-28). It is also respectfully urged that the subject matter of claim 1 as amended has previously been considered by the Examiner, since the use of the terms, "particle size" and "lyophilized" in the prior iteration of this claim make it clear that this is a particulate medium, despite any contrary misunderstanding on the part of the Patent Office. Claim 1 has simply been rephrased to avoid any further misunderstanding. Thus, entry of amended claim 1 is respectfully requested. Claims 14 and 15 are amended to replace the term, "L-cysteine/cystine" with "L-cysteine or cystine," to more clearly conform to U.S. practice.

Attorney Docket No. 408-016A

In response to the request by the Examiners for clarification of support for certain elements of claim 1, it is also noted that the ordinary artisan will appreciate that the amino acids employed in the claimed medium are not in solution. Amino acids are water soluble, and the entire specification makes it clear that the amino acids in question are lyophilized and in particulate form. For instance, Example 1, explains at page 5, lines 23-35 that:

The commercial amino acid preparation was obtained from the company Frsnius-Kabi France S.A. It has the following composition, qs for 1 L of water PPI:

After providing the analysis of the commercial amino acid preparation in solution, the specification then explains, at page 6, lines 16-18 that,

The solution is lyophilised and the lyophilisate collected is screened through a vibrating screen with a pore size of 250  $\mu\text{m}$ .

At page 6, lines 19-28, the specification explains that, the medium is prepared as follows.

252 g of screened wheat germs, 252 g of screened yeasts, 90 g of the lyophilised and screened amino acid solution, 5.4 g of screened cyanocobalamine and 0.6 g of D-biotin are weighed, the whole is homogenised in a homogeniser and then passed through a screen with a mesh size of 400  $\mu\text{m}$ . The medium is packaged in labelled stoppered bottles and can be kept in a cold room at temperatures between +2° C. and +8° C.

The text preceding the above-quoted section of Example 1 also makes it clear that the additional components of wheat germ, vitamins and yeasts are in powdered form and passed through a 250  $\mu\text{m}$  screen. The description of the method of culture has no step or mention of preparing a solution of the medium. Instead the medium is employed directly as prepared in particulate form. In order to address a further question raised by the Examiners, it is submitted that the amino acids employed are free amino acids, and are not in the form of proteins or peptides. It is urged that the ordinary artisan who has read the instant specification will not consider that any reference to "amino acids" in any way encompasses non-hydrolyzed proteins.

At page 3 of the Office Action, the Examiner has maintained the rejection of claims 1 and 4-5 under 35 U.S.C 102(b) and/or 35 U.S.C 103(a), as allegedly unpatentable over Rodriguez et al. (Rodriguez). The Examiner takes the position that Rodriguez anticipates the claimed invention by teaching "a medium for cultivating [or] producing mites comprising amino acids in lyophylized form." The Examiner further asserts that even if Rodriguez fails to anticipate the invention as claimed, "[i]t would have been obvious...to provide for a medium comprising lyophylized amino acids for which to culture mites." At page 4 of the Office Action, the

Attorney Docket No. 408-016A

Examiner takes the position that the statement in claim 1 requiring that the medium be "free from human or animal substances" is part of the preamble, and therefore does not operate to distinguish claim 1 from the teaching of Rodriguez.

Applicants respectfully disagree. The law regarding the effect of a preamble requires that the alleged preamble be employed as a limitation when necessary to preserve the validity of the claim. However, in the interest of expeditious prosecution, and in order to particularly set forth that which Applicants consider to be their invention, claim 1 is amended to include the requirement that the medium be, "free from human or animal substances" in the body of the claim.

For this reason, and based on the position taken by the Examiner on page 4, lines 15-19, of the Office Action, it is respectfully submitted that claim 1 is clearly distinguished from the teachings of Rodriguez.

In addition, Rodriguez teaches at page 979, under the heading, "Materials and Methods" that the subject mites were cultured on a dog food medium. Table 1, at page 982, relied on by the Examiner, does not teach the use of an amino acid medium according to claim 1, but instead simply reports the amino acid content of the mites grown on the previously noted dog food medium. The title bar of Table 1 states: "Analysis of Adult Female *T. putrescentiae* cultured in Dog Food."

At the top of page 4 of the Office Action, the Examiner has also pointed to Table 2, on page 983 of Rodriguez. However, Table 2 and page 981, lines 34-38, merely describe a liquid diet containing amino acids. Rodriguez does not report that the amino acids are in a nonsolubilized particulate form with a size of less than 250 microns. In addition, since the medium of Table 2 is in liquid form (the units are reported in "g/100ml"), the medium of Table 2 does not describe or suggest a particulate lyophilized medium.

The Examiner has argued, at page 5 of the Office Action, that the wording of claim 1 "does not necessarily mean that the medium itself is in lyophilized form." The Examiner is respectfully urged to consider the background discussion in the present specification. There, e.g., at page 1, lines 14-34, the conventional culture of mites on dry media such as skin scales, shrimp eggs or powdered pig's liver, is detailed. Thus, the ordinary artisan would have known that mites can be cultured on a dry medium. The use of the terms, "particulate" and "lyophilized" in claim 1 make this even more clear, since it is submitted that lyophilized particles of amino acids, once in contact with liquid water, are no longer lyophilized, even if they are not fully dissolved. With the rewording of claim 1, it is respectfully submitted that the

Attorney Docket No. 408-016A

meaning of claim 1 is clearly unambiguous.

There is no reference of record to remedy these clear deficiencies in the Rodriguez reference. If the Examiner has based her alternative rejection over Rodriguez under 35 U.S.C. 103(a) on personal information or knowledge, she is respectfully invited to make such personal information or knowledge of record in a Declaration Under 37 C.F.R. 1.132.

In addition, even though no art has been made of record that describes the use of amino acids as mite culture medium, it is helpful to consider the Declaration Under Rule 132 by Thierry Batart, that has already been made of record. That Declaration provides a comparison of the growth of mites on human skin scales (human squames) verses culture of mites on crystalline amino acids (untreated amino acids). Figure 1A, 1B and 1C clearly confirm that untreated amino acids yielded poor growth relative to growth of mites on human skin scales. Page 4 of the Declaration describes the data provided by Tables 1, 2 and 3 of the specification (pages 9-10 of the specification) and attests to the superiority of the medium with lyophilized, particulate amino acids relative to untreated amino acids.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

At page 7 of the Office Action, the Examiner has maintained the rejection of claims 2-3, 6-10, 12-15 and 20 under 35 U.S.C. 103(a) as allegedly unpatentable over Rodriguez in view of newly cited Singh, Yi et al. (Yi) and Miyamoto et al (Miyamoto). Singh is stated to describe various salts and vitamins. Yi is stated to describe *Dermatophagoids pteronyssinus* and *Blomia tropicalis*. The Examiner takes the position that claims 2-3, 6-10, 12-15 and 20 differ from the description of Rodriguez only in that specific salts and the specific strain of mites are not disclosed by Rodriguez.

Applicants respectfully disagree. The Examiner's attention is respectfully directed to the many shortcomings of Rodriguez discussed above in response to the rejection under 35 U.S.C 102(b)/103(a). Claims 2-3, 6-10, 12-15 and 20 all depend from claim 1, and therefore incorporate all of the elements of claim 1. Rodriguez fails to teach a "[a] medium for cultivating and producing mites that comprises effective amounts of a plurality of amino acids in lyophilized form with a particle size of less than 250  $\mu$ m, wherein the medium is in particulate form and free from human or animal substances."

At most, Singh discusses the general definition of an artificial diet for insects, and identifies the background literature, without seeming to provide any specific formulations. Yi teaches culture of mites on fine powdered fish food (page 190, left column). Miyamoto teaches

Attorney Docket No. 408-016A

culture of mites on dried yeast, powdered mouse feed and dried fish powder. Nowhere is there any teaching or suggestion of record to culture mites on the media as set forth by claim 1.

If the Examiner has based her rejection under 35 U.S.C. 103(a) on personal information or knowledge that might be argued to remedy any of these clear deficiencies, she is respectfully invited to make such personal information or knowledge of record in a Declaration Under 37 C.F.R. 1.132.

For all of these reasons, reconsideration and withdrawal of this ground of rejection is respectfully requested.

In view of the foregoing, it is respectfully submitted that the Application is in condition for allowance based on the previously filed Remarks and materials and reconsideration and allowance are respectfully requested.

Should any extensions of time or fees be necessary in order to maintain this Application in pending condition, appropriate requests are hereby made and authorization is given to Debit Account No. 02-2275.

Respectfully submitted,

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